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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,519	06/06/2001	Timothy C. Farries	4-30443B/D1	6920

1095 7590 01/16/2004

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/875,519	Applicant(s) FARRIES ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/142,334, which is a 371 continuation of PCT/GB97/00603.

Claims 1-56 have been canceled previously.

Claim 57 has been canceled herewith.

Claim 58 has been added, is currently pending and is the subject of examination in the present Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA sequence encoding a modified human C3 protein of SEQ ID NO: 22 with one or more of the following mutations: E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, and REA1591-3stop, does not reasonably provide enablement for a DNA sequence encoding any modified human C3 protein comprising all frame shift mutations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

It was previously stated: "Claim 57 is a rewritten version of previous claim 55 and is drawn to a DNA sequence encoding a modified human C3 protein which is capable of forming a stable C3 convertase comprising one or more of the mutations E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, REA1591-3stop or frame shift.

However, while the specification may be enabling for a particular frame shift mutation, the claim as drafted reads on any frame shift mutation within the sequence of the modified C3 protein. The specification does enable the full scope of frame shift mutations within C3, as only a limited number of examples are disclosed and the artisan is not provided sufficient guidance by the specification in regards to the structure and/or functional characteristics of other frame shift mutations which may occur or be engineered into the C3 molecule. Further, the only sequence for which the specification teaches that the unmodified residues (e.g., 'E' of E992S) are located at the recited positions (e.g., '992' of E992S) for the aforementioned modifications (e.g., 'S' of E992S) is SEQ ID NO: 22. It would require an undue amount of experimentation on the part of the artisan to determine whether such modifications could be made any C3 protein, including human proteins which an artisan might generically term "C3," or would be effectively equivalent to modifications of SEQ ID NO: 22 without specific guidance from the

Art Unit: 1644

specification. Redrafting the claim to recite SEQ ID NO: 22 and specific frame shift mutations can overcome this ground of rejection.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue experimentation to practice the claimed invention."

Applicant's arguments filed October 14, 2003 have been fully considered but they are not persuasive.

Claim 58 is a rewritten version of previous claim 57 and is drawn to a DNA sequence encoding a modified human C3 protein of SEQ ID NO: 22 with one or more of the mutations E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, and REA1591-3 stop. Applicant contends that the amendment to the claim overcomes the ground of rejection. The Examiner respectfully disagrees with Applicant's position. While the modified protein must comprise at least one of the listed mutations, the claim is still written in an open format embracing additional modifications/mutations not enabled by the specification. It is suggested that the claim be amended to recite the mutations as a closed Markush group in a manner such as the following:

A DNA sequence encoding a modified human C3 protein of SEQ ID No: 22, wherein the modification consists of one or more mutations selected from the group consisting of: E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, and REA1591-3 stop.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can

Art Unit: 1644

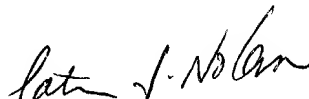
normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D. 

Patent Examiner

January 11, 2004



PATRICK J. NOLAN, PH.D.

PRIMARY EXAMINER

1/12/04